Medtronic

MRI Guidelines for InterStim Therapy neurostimulation systems

Instructions for use

! USA Rx only

CE 0123

Explanation of symbols on product or package labeling
Refer to the appropriate product for symbols that apply.

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.

Authorized representative in the European community

Manufacturer

For USA audiences only

Magnetic Resonance (MR) Conditional

Magnetic Resonance (MR) Unsafe

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Refer to the Indications Insert for indications and related information.

Refer to the appropriate Information for Prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

Description

MR scanning conditions

MR Conditional: Non-clinical testing has demonstrated that InterStim Therapy systems have been found to be MR Conditional. If this patient is implanted with an InterStim II Model 3058 Neurostimulator or an eligible serial number of an InterStim Model 3023 Neurostimulator (when implanted as a system including a neurostimulator, lead, and extension as applicable), MRI examinations of the head only may be safely performed under the following conditions:

- 1.5-Tesla (T) horizontal closed bore
- Maximum spatial gradient of 19 T/m (1900 gauss/cm)
- RF transmit/receive head coil only (no RF transmit body coil)
- Gradient slew rate limited to 200 T/m/s
- Normal operating mode (Scanning frequency of approximately 64 MHz only)
- If possible, do not sedate the patient
- Model 3058 and eligible Model 3023 Neurostimulators: Turn the neurostimulator off
- Eligible Model 3023 Neurostimulators only: Disable the magnet switch

Scanning under different conditions may result in severe patient injury or device malfunction.

MRI and InterStim Therapy

It is important to read this information in its entirety before conducting a magnetic resonance imaging (MRI) head scan on a patient with any implanted component of a Medtronic InterStim Therapy neurostimulation system. These instructions do not apply to other implantable products, or other devices, products, or items. Contact Medtronic at the appropriate address or phone number listed at the back of this manual if you have any questions.

MRI systems generate powerful electromagnetic fields that can produce a number of interactions with implanted components of the neurostimulation system. Some of these interactions, especially heating, are potentially hazardous and can lead to serious or permanent patient injury. The following information describes the potential interactions and control measures that should be taken to minimize the risks from these interactions.

Information for prescribers

Warnings

MRI during test stimulation – Explant all test stimulation components if an MRI scan is required. Physicians should not prescribe MRI for patients undergoing test stimulation or who have any neurostimulation system components that are not fully implanted. MRI has not been evaluated with test stimulation components. The external neurostimulator

contains ferromagnetic material, which can be affected by the MRI magnet and is unsafe in the MRI environment.

MRI RF transmit body coil – Do not use an RF transmit body coil or a receive-only head coil. Serious patient injury could result.

MRI transmit/receive head coil – An MRI examination of the head only (no other part of the body has been tested) can be conducted safely using an RF transmit/receive head coil when all instructions in this manual are followed.

Limitations –

- These instructions apply only to Medtronic InterStim Therapy neurostimulation systems for approved indications listed as eligible for an MRI head scan.
- Prior to an MRI head scan, determine whether the patient has multiple active medical device implants (such as deep brain stimulation systems, implantable cardiac defibrillators, and others). The most restrictive MRI exposure requirements must be used if the patient has multiple active medical device implants. Contact the appropriate device manufacturers if you have questions. If you are unclear what implants may be present, perform an x-ray to determine implant type and location.
- Scans must be limited to 1.5-T horizontal closed bore MRI systems. Use of different MRI systems (such as open bore or 3.0-T MRI) is not permitted because it may expose the patient to unacceptable or unknown risks.
- Do not place any part of the implanted system within the RF transmit/receive head coil. Excessive heating can cause tissue damage and result in serious or permanent patient injury.
- If the system is removed, remove all portions of the neurostimulation system to allow for future MRI scans. Even partial systems can have MRI interactions such as RF heating. Excessive heating can cause tissue damage and result in serious or permanent patient injury.

Risks associated with MRI examination – Exposing a patient with an implanted neurostimulation system or component to MRI settings other than those listed in this manual may potentially injure the patient or damage the neurostimulator. The known potential risks are as follows:

- Induced electrical currents from the MRI to the neurostimulation system or component may cause heating, especially at the lead-electrode site, resulting in tissue damage.

Note: This warning applies even if only a lead or extension is implanted.

Factors that increase the risks of heating and tissue damage include, but are not limited to, the following:

– Higher MRI Specific Absorption Rate (SAR) RF power levels.

– MRI RF transmit/receive coil that is near or extends over the implanted lead, including abandoned leads or portions of leads.

- Induced electrical currents may also stimulate or shock the patient, depending on the potential circuit paths, the exposure to the pulsed gradient magnetic fields, and the pulsed RF field.
- The static magnetic field, pulsed gradient magnetic field, and/or the pulsed RF field generated by MRI may permanently damage the neurostimulator, requiring explant or replacement.
- MRI may affect the operation of the neurostimulator. MRI may also reset the parameters to power-on-reset (POR) settings, requiring reprogramming with the clinician programmer.
- The neurostimulator may move within the implant pocket and align itself with the MRI field, which may cause patient discomfort.

Precautions

Obtain the latest MRI guidelines – Always obtain the latest MRI guidelines. Refer to the contact information on the last page of this manual, or go to www.medtronic.com/mri.

Enter the neurostimulator model on the website (www.medtronic.com/mri) to obtain the latest version of the manual containing these guidelines. Copies of these MRI guidelines may not be the most up-to-date version if not received directly from the website or in another manner from Medtronic at the time of the patient's MRI appointment.

External devices are MR Unsafe in the MRI environment – Do not bring any of the following Medtronic external control devices into the MRI scanner room:

- Patient programmer
- Clinician programmer
- Control magnet

These devices contain ferromagnetic material, which can be affected by the MRI magnet and are unsafe in the MRI environment.

Normal operating mode (MRI scans) – Use only Normal operating mode when conducting an MRI head scan. Scans conducted using other modes (eg, First level controlled operating mode) may increase the risk of shocking sensations/uncomfortable stimulation or unusual sensations during MRI scans.

Gradient limitation – Limit the gradient slew rate to 200 T/m/s or less. Exposure to gradient systems with a gradient slew rate exceeding 200 T/m/s may result in overstimulation or shocking, particularly for unipolar-capable devices.

Scanning frequency of approximately 64 MHz only – Do not conduct MRI scans with nonproton scanning frequencies (such as, 13C, 23Na, or 31P). Frequencies other than 64 MHz have not been tested.

RF transmit/receive head coil only – Use a transmit/receive head coil to limit RF exposure to the head only and ensure that the neurostimulator is well outside of the RF field. Do not use a receive-only head coil because it increases the risk of heating and potential nerve and tissue damage during MRI scans.

Neurostimulator settings during the MRI examination – Before conducting an MRI scan, turn the neurostimulator off. For the Model 3023 Neurostimulator, disable the Magnet

Switch. Failure to use these settings could result in uncomfortable, unintended stimulation during the MRI examination. If the neurostimulator is not turned off or cannot be confirmed to be off, the scan should not be performed unless it is a medical emergency and the risk of uncomfortable, unintended stimulation (often described as shocking or jolting sensation) is justified.

Ensure that the electrodes remain off during the MRI scan by turning the neurostimulator off. If the neurostimulator cannot be turned off (eg, because the battery is depleted, which may occur in an abandoned or unused system) and the neurostimulator programmed in a unipolar configuration (ie, the case is programmed as a positive electrode) is on during the MRI examination, the likelihood of undesired MRI-induced effects (eg, shocking and jolting) increases dramatically.

Patient interaction during MRI – If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination. Monitor the patient during the MRI examination. Verify that the patient is feeling normal and is responsive between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient experiences any heating, pain, shocking sensations/uncomfortable stimulation, or unusual sensations.

Serial numbers ineligible for MRI scans (Model 3023 Neurostimulator only) – Due to increased risk of neurostimulator damage, patients implanted with InterStim Model 3023 Neurostimulators with the following serial numbers should not have MRI scans:

- Less than NBV132955H
- Between NBV133037H and NBV133063H
- Between NBV628045S and NBV628263S

Control magnet function after MRI (Model 3023 Neurostimulator only) – Do not conduct an MRI scan if the patient can only use a control magnet to turn the neurostimulator on or off. An MRI scan may permanently damage the magnet switch in the neurostimulator. If the magnet switch in the neurostimulator is damaged, the patient will require a patient programmer to turn the neurostimulator on or off.

MRI head scan using an RF transmit/receive head coil

MR When all of the instructions stated in this manual are followed, MRI examinations of the head only using a 1.5-T horizontal closed bore MRI system with an RF transmit/receive head coil may be safely performed.

Preparing for an MRI head scan

Prior to performing an MRI head scan on a Medtronic InterStim Therapy patient:

1. Determine whether the patient has any other implants or conditions that would prohibit or contraindicate an MRI examination. The most restrictive MRI exposure requirements must be used if the patient has multiple active medical device implants. Contact the appropriate device manufacturers if you have questions.
   If the following requirements cannot be met, do not proceed with the MRI examination.

2. Verify the implant location of the InterStim Therapy system and ensure that the InterStim Therapy system will not be inside the transmit/receive head coil. Do not use the RF transmit body coil.
   Note: When implanted per approved indications, InterStim Therapy components are outside of the head coil.
3. Inform the patient of the risks of undergoing an MRI.
   Note: Patients should always inform healthcare personnel that they have an implanted neurostimulation system before any medical procedure begins.
4. If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination.
5. If the patient does not use a Model 3037 Patient Programmer, instruct the patient to see the implanting physician or managing physician to confirm MRI head scan eligibility (refer to Table 1) and neurostimulator settings for MRI (refer to Table 2) using the Model 8840 Clinician Programmer.
6. Determine the implanted neurostimulator model. Check the current Patient ID card or use the InterStim iCon Model 3037 Patient Programmer or N'Vision Model 8840 Clinician Programmer.
   Note: Refer to the "InterStim iCon Model 3037 Patient Programmer instructions" on page 11 or the appropriate programmer manual for additional instructions for use.
7. Review Table 1 and use the implanted neurostimulator model to determine MRI head scan eligibility. Eligibility for an MRI head scan is limited to specific neurostimulator models and serial number series.

Table 1. MRI head scan eligibility by neurostimulator model

Model	Description	Eligibility details
3058	InterStim II	All Model 3058 Neurostimulators (serial numbers beginning with NJY) are eligible for head-coil only MRI scans.
3023	InterStim	Check the serial number. No MRI scans if the serial number is:[a] ▪ Less than NBV132955H ▪ Between NBV133037H and NBV133063H ▪ Between NBV628045S and NBV628263S
7427T	InterStim Twin	No MRI scans.

[a] If a programmer is used to check the neurostimulator serial number, the letter suffix (H or S) may not appear.

8. Using the eligible neurostimulator model, review Table 2 and use the appropriate programmer to change or verify the program settings to comply with neurostimulator settings for an MRI head scan.

Note: Before changing a neurostimulator program setting, record the current setting so that the neurostimulator can be programmed to pre-MRI program settings following the MRI examination.

Table 2. Recommended neurostimulator settings for an MRI head scan

Model	Programmer	Settings
3058	Model 3037 Patient Programmer	Turn the neurostimulator off.
3023	Model 8840 Clinician Programmer	Turn the neurostimulator off and disable the magnet switch.[a]

[a] For the Model 3023 Neurostimulator, the Model 8840 Clinician Programmer is required to disable the magnet switch. If you have verified that the magnet switch has been disabled, the Model 3037 Patient Programmer may be used to turn the neurostimulator off.

Note: For an emergency MRI head scan on a patient implanted with the Model 3023 Neurostimulator: If an emergency MRI head scan is required and the Model 8840 Clinician Programmer cannot be used to change or verify neurostimulator settings:

- Use the Model 3037 Patient Programmer to turn the neurostimulator off and reduce the amplitude to 0.0 V.
- If the magnet switch is enabled, the patient may experience uncomfortable or unintended stimulation during the MRI scan.
- If an active program with bipolar electrode settings is used (bipolar mode), the likelihood of uncomfortable stimulation during an MRI scan will be reduced.
- The patient should be instructed to see the implanting physician or managing physician to verify neurostimulator function after the MRI head scan.

9. Ensure that the head coil is a transmit/receive head coil.
   Note: If you are unsure if your MRI system has RF transmit/receive head coil capability, check with the MRI equipment manufacturer. Do not use a receive-only head coil or an RF transmit body coil because of the risk of heating and potential nerve and tissue damage during MRI scans.
10. Instruct the patient to immediately inform the MRI operator if any discomfort, unexpected stimulation, shocking, or heating occurs during the examination.
11. Verify that all proposed MRI examination parameters comply with the MR scanning conditions on page 5 of this manual. If these conditions cannot be met, do not proceed with the MRI examination.

During an MRI head scan

- Conduct the MRI head scan in Normal operating mode only. Do not scan in First level controlled operating mode because higher SAR and gradient levels are permitted.

- Monitor the patient both visually and audibly. Check the patient between each imaging sequence. Discontinue the MRI examination immediately if the patient reports any problems or has any discomfort.
- During the MRI head scan, the patient may feel tugging and/or vibration of the neurostimulator. If the tugging or vibration causes the patient considerable discomfort, stop the MRI head scan.

After an MRI head scan

- Verify that the patient has not experienced adverse effects as a result of the MRI head scan. Contact Medtronic to report any adverse effects.
- Restore the neurostimulator settings to pre-MRI head scan values.
- Instruct the patient to see the implanting physician or managing physician:
  - if the patient has any questions about neurostimulator function
  - if assistance is required to return program parameters to pre-MRI head scan settings
  - if the patient programmer displays a power-on-reset (POR) screen

Patient programmer instructions for MRI technicians

These instructions are for the use of the InterStim iCon Model 3037 Patient Programmer at the patient's MRI appointment. For additional instructions, refer to the Model 3037 Patient Programmer user manual.

InterStim iCon Model 3037 Patient Programmer instructions

Figure 1. *Model 3037 Patient Programmer keys.*

Synchronizing the programmer and neurostimulator

Hold the programmer over the neurostimulator and press the **Sync** key.

Viewing the neurostimulator model and serial number

To view the neurostimulator model (IM) and serial number (IS) information screens:

1. Synchronize the programmer and neurostimulator.
2. If using the patient's Model 3037 Patient Programmer, press the **Up** arrow on the **Navigator** key.
3. Press the **Left** arrow on the **Navigator** key once to select information screens.
4. Press the **Down** arrow on the **Navigator** key.
5. Press the **Left** or **Right** arrows on the **Navigator** key to scroll through each information screen until the neurostimulator model (IM) or serial number (IS) screens appear (Figure 2).

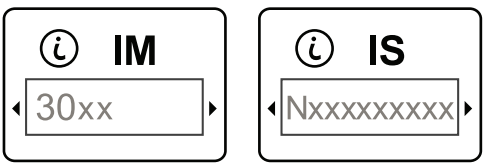

Figure 2. *Neurostimulator model and serial number information screens.*

Note: Refer to Table 1 for information about using the neurostimulator model and serial number when determining MRI head scan eligibility.

Turning the neurostimulator on or off

To turn the neurostimulator on or off, hold the programmer over the neurostimulator and press the **Neurostimulator on** or **off** key (Figure 3).

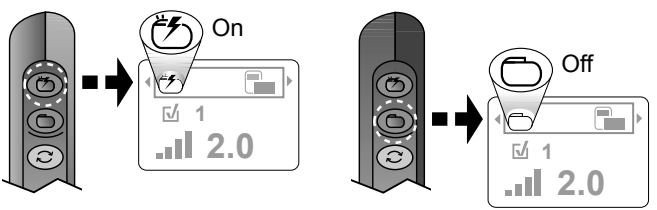

Figure 3. *Neurostimulator on and off keys.*

Changing a program

1. Synchronize the programmer and neurostimulator.
2. Select a program.
3. Synchronize the programmer and neurostimulator.
4. Verify that the program is active ☑.

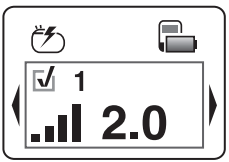

Figure 4. *Programmer screen showing an active program.*

Increasing or decreasing amplitude

1. Synchronize the programmer and neurostimulator.
2. While holding the programmer over the neurostimulator:
   - Press the **Decrease** key to decrease amplitude.
   - Press the **Neurostimulator on** key and then press the **Increase** key to increase amplitude.

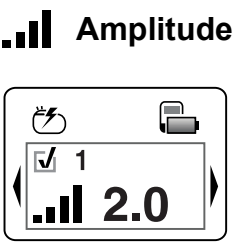

Figure 5. *Programmer screen showing an amplitude of 2.0 V.*

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Contacts for specific countries are listed inside this cover.

M947945A002

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